# Foreword

This manual and the equipment it describes are for use only by qualified medical professionals trained in the particular technique and surgical procedure to be performed. This manual is intended as a guide for servicing the AEM Monitor, including its setup and operation. It is not intended to be a general reference about the use of electrosurgery either in general application or in laparoscopic procedures.

**Caution**

Read and review all instructions in this manual prior to using the AEM system.

**Caution**

FEDERAL (USA) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

**Caution**

THE AEM MONITOR IS DESIGNED TO SAFELY DELIVER ELECTROSURGICAL ENERGY AND TO PREVENT INJURY CAUSED BY INSULATION FAILURE AND CAPACITIVE COUPLING. THE ENCISION AEM MONITOR IS NOT INTENDED TO TEST FOR INSULATION DAMAGE ON LAPAROSCOPIC INSTRUMENTS. DO NOT ATTEMPT TO USE THIS SYSTEM AS AN INSTRUMENT INSPECTION TOOL.

## Conventions Used in this Manual

**Warning**

INDICATES A POTENTIALLY HAZARDOUS SITUATION WHICH, IF NOT AVOIDED, COULD RESULT IN SERIOUS INJURY OR DEATH.

**Caution**

INDICATES A HAZARDOUS SITUATION WHICH, IF NOT AVOIDED, MAY RESULT IN MINOR OR MODERATE INJURY.

**Notice**

INDICATES A HAZARD WHICH MAY RESULT IN PRODUCT DAMAGE.

Controls, indicators, and receptacles on the unit appear in bold and/or italic capitals like this:

**RETURN ELECTRODE,** ***RETURN ELECTRODE, Return Electrode***

# Warnings and Cautions

Please refer to the manual of your electrosurgical generator for applications information including warnings and precautions regarding its use before proceeding further.

### Explosion, Fire and Shock Hazards

**Warning**

EXPLOSION HAZARD. DO NOT USE ELECTROSURGERY IN THE PRESENCE OF FLAMMABLE ANESTHETICS.

FIRE/EXPLOSION HAZARD. THE FOLLOWING SUBSTANCES WILL CONTRIBUTE TO INCREASED FIRE AND EXPLOSION HAZARDS IN THE OPERATING ROOM:

- FLAMMABLE SUBSTANCES (SUCH AS ALCOHOL BASED SKIN PREPPING AGENTS AND TINTURES).
- NATURALLY OCCURRING FLAMMABLE GASES WHICH MAY ACCUMULATE IN BODY CAVITIES SUCH AS THE BOWEL.
- OXYGEN AGENTS (SUCH AS NITROUS OXIDE [$N_2O$] ATMOSPHERES).

THE SPARKING AND HEATING ASSOCIATED WITH ELECTROSURGERY CAN PROVIDE AN IGNITION SOURCE. OBSERVE FIRE PRECAUTIONS AT ALL TIMES. WHEN USING ELECTROSURGERY IN THE SAME ROOM WITH ANY OF THESE SUBSTANCES OR GASES, PREVENT THEIR ACCUMULATION OR POOLING UNDER SURGICAL DRAPES, OR WITHIN THE AREA WHERE ELECTROSURGERY IS PERFORMED.

FIRE HAZARD. DO NOT USE EXTENSION CORDS.

FIRE HAZARD. FOR CONTINUED PROTECTION AGAINST FIRE HAZARD REPLACE FUSES ONLY WITH THE SAME TYPE AND RATING.

FIRE HAZARD. ELECTROSURGICAL ACCESSORIES THAT ARE ACTIVATED OR HOT FROM USE CAN CAUSE A FIRE. DO NOT PLACE THEM NEAR OR TOUCHING FLAMMABLE MATERIALS (SUCH AS GAUZE OR SURGICAL DRAPES).

ELECTRIC SHOCK HAZARD. CONNECT THE GENERATOR POWER CORD TO A PROPERLY GROUNDED RECEPTACLE. DO NOT USE POWER STRIP PLUG ADAPTERS.

ELECTRIC SHOCK HAZARD. ENSURE THAT ALL ACCESSORIES, CORDS, AND ADAPTERS ARE CORRECTLY CONNECTED AND THAT NO METAL IS EXPOSED.

ELECTRIC SHOCK HAZARD. DO NOT CONNECT A WET POWER CORD TO THE AEM MONITOR OR TO THE WALL RECEPTACLE.

ELECTRIC SHOCK HAZARD. ALWAYS UNPLUG THE AEM MONITOR BEFORE CLEANING.

## General Electrosurgical Hazards

### Warning

ANY ELECTROSURGICAL PROCEDURE IS SAFEST IF MODERATE CONTROL SETTINGS ARE USED ALONG WITH MINIMUM ACTIVATION TIMES. PROLONGED ACTIVATIONS WITHOUT THE ELECTRODE IN CONTACT WITH THE TISSUE SHOULD BE AVOIDED.

CONFIRM PROPER ELECTROSURGICAL POWER SETTING BEFORE PROCEEDING WITH SURGERY. USE THE LOWEST POWER SETTING THAT ACHIEVES THE DESIRED SURGICAL EFFECT.

IN ORDER TO LESSEN THE POSSIBILITY OF CREATING UNINTENDED BURNS, ACTIVATE THE ELECTROSURGICAL GENERATOR ONLY WHEN THE ACTIVE ELECTRODE IS NEAR OR TOUCHING THE TARGET TISSUE.

THE SAFE USE OF MONOPOLAR ELECTROSURGERY REQUIRES PROPER PLACEMENT OF THE PATIENT RETURN ELECTRODE. TO AVOID ELECTROSURGICAL BURNS BENEATH THE PATIENT RETURN ELECTRODE, FOLLOW ALL DIRECTIONS ON THE PRODUCT PACKAGE FOR PROPER RETURN ELECTRODE PLACEMENT AND USE.

IN SOME CIRCUMSTANCES, POTENTIAL EXISTS FOR ALTERNATE SITE BURNS AT POINTS OF SKIN CONTACT (E.G., BETWEEN THE ARM AND THE SIDE OF THE BODY). THIS OCCURS WHEN ELECTROSURGICAL CURRENT SEEKS A PATH TO THE PATIENT RETURN ELECTRODE THAT INCLUDES THE SKIN TO SKIN CONTACT POINT. CURRENT PASSING THROUGH SMALL SKIN TO SKIN CONTACT POINTS IS CONCENTRATED AND MAY CAUSE A BURN. THIS IS TRUE FOR EARTH REFERENCED AND ISOLATED OUTPUT GENERATORS.

TO REDUCE THE POTENTIAL FOR ALTERNATE SITE SKIN BURNS, DO ONE OR MORE OF THE FOLLOWING:

- ❑ AVOID SKIN TO SKIN CONTACT POINTS, SUCH AS FINGERS TOUCHING LEG, WHEN POSITIONING THE PATIENT.
- ❑ PLACE TWO TO THREE INCHES OF DRY GAUZE BETWEEN CONTACT POINTS TO ENSURE THAT CONTACT DOES NOT OCCUR.
- ❑ POSITION THE PATIENT RETURN ELECTRODE TO PROVIDE A DIRECT CURRENT ROUTE BETWEEN THE SURGICAL SITE AND THE RETURN ELECTRODE WHICH AVOIDS SKIN-TO-SKIN CONTACT.
- ❑ IN ADDITION, PLACE PATIENT RETURN ELECTRODES ACCORDING TO THE MANUFACTURER'S INSTRUCTIONS.

WHILE USING ELECTROSURGERY, THE PATIENT SHOULD NOT BE ALLOWED TO COME INTO DIRECT CONTACT WITH GROUNDED METAL OBJECTS (E.G., SURGICAL TABLE FRAME, INSTRUMENT TABLE, ETC.). IF THIS IS NOT POSSIBLE DURING CERTAIN PROCEDURES (E.G., THOSE IN WHICH NONINSULATED HEAD FRAMES ARE USED), USE EXTREME CAUTION TO MAXIMIZE PATIENT SAFETY:

- ❑ USE THE LOWEST POWER SETTING THAT ACHIEVES THE DESIRED EFFECT.
- ❑ PLACE THE PATIENT RETURN ELECTRODE AS CLOSE TO THE SURGICAL SITE AS POSSIBLE.
- ❑ PLACE DRY GAUZE BETWEEN THE PATIENT AND THE GROUNDED OBJECT IF POSSIBLE.
- ❑ CONTINUALLY MONITOR THE CONTACT POINT(S).

KEEP ELECTRICAL CONNECTIONS DRY WHILE IN USE TO PREVENT POTENTIAL CONDUCTION OF HF CURRENT TO THE USER.

## General Electrosurgical Hazards, continued.

### Warning

POTENTIALLY HAZARDOUS CONDITIONS MAY EXIST WHEN ACCESSORIES OF SIMILAR CONNECTOR TYPES ARE INTERMIXED. BE CERTAIN THAT ACCESSORIES ARE APPROPRIATE FOR THE TYPE OF ELECTROSURGICAL GENERATOR OUTPUT USED AND THE INTENDED APPLICATION.

## Active Accessories and AEM Monitor

### Warning

THESE DEVICES HAVE BEEN SPECIFICALLY DESIGNED FOR USE IN LAPAROSCOPY. DO NOT USE FOR OTHER PROCEDURES.

DO NOT WRAP ACCESSORY CORDS AROUND METAL OBJECTS. WRAPPING CORDS AROUND METAL OBJECTS MAY INDUCE CURRENTS THAT COULD LEAD TO SHOCKS, FIRES OR INJURY.

THE ELECTRODE TIP MAY REMAIN HOT ENOUGH TO CAUSE BURNS AFTER THE ELECTROSURGICAL CURRENT IS DEACTIVATED.

WHEN NOT IN USE, PLACE ACCESSORIES IN A CLEAN, DRY, NONCONDUCTIVE AND HIGHLY VISIBLE AREA NOT TOUCHING THE PATIENT. INADVERTENT CONTACT WITH THE PATIENT MAY RESULT IN BURNS.

INADVERTENT ACTIVATION OR MOVEMENT OF THE ACTIVATED ELECTRODE TIP OUTSIDE THE FIELD OF VISION MAY RESULT IN INJURY TO THE PATIENT. USE THESE INSTRUMENTS ONLY UNDER CONDITIONS THAT ASSURE ADEQUATE VISUALIZATION.

LOCALIZED BURNS TO THE PATIENT OR PHYSICIAN MAY COME FROM ELECTRICAL CURRENTS CARRIED THROUGH CONDUCTIVE OBJECTS (SUCH AS CANNULAS OR SCOPES). ELECTRICAL CURRENT MAY BE GENERATED IN CONDUCTIVE OBJECTS BY DIRECT CONTACT WITH THE ACTIVE ACCESSORY CABLE BEING IN CLOSE PROXIMITY TO THE CONDUCTIVE OBJECT.

ENSURE THAT THE INSULATION OF CONVENTIONAL, NONSHIELDED DISPOSABLE AND REUSABLE LAPAROSCOPIC INSTRUMENTATION IS INTACT. COMPROMISED INSULATION OF NONSHIELDED INSTRUMENTS MAY LEAD TO SHOCKS OR BURNS TO THE PATIENT OR SURGICAL PERSONNEL.

WHEN USING LAPAROSCOPIC INSTRUMENTATION WITH METAL CANNULAS, THE POTENTIAL EXISTS FOR ABDOMINAL WALL BURNS TO OCCUR IN THE EVENT OF DIRECT ELECTRODE TIP CONTACT TO THE CANNULA.

REFER TO THE CANNULA MANUFACTURER'S INSTRUCTIONS BEFORE INSERTING THE ELECTRODE INTO THE CANNULA. TO AVOID DAMAGING THE ELECTRODE OR INJURING THE PATIENT, INSERT AND WITHDRAW THEM CAREFULLY.

**Active Accessories and AEM Monitor, continued.**

## Warning

INSPECT CORDS FOR BREAKS, CRACKS, NICKS OR OTHER DAMAGE BEFORE EVERY USE. ENSURE THAT END OF LIFE INDICATORS ARE NOT PRESENT. IF ANY OF THESE ARE PRESENT, DO NOT USE. FAILURE TO OBSERVE THIS PRECAUTION MAY RESULT IN INJURY OR ELECTRICAL SHOCK TO THE PATIENT OR OPERATING PERSONNEL .

DAMAGED EXTERNAL INSULATION ON INSTRUMENTS AND INCORRECT SETUP OF THE AEM MONITOR MAY RESULT IN A RISK OF UNINTENDED PATIENT BURN. DO NOT USE PRODUCT HAVING DAMAGED INSULATION.

## Caution

READ THE INSTRUCTIONS, WARNINGS, AND CAUTIONS PROVIDED WITH THE AEM MONITORING SYSTEM ACCESSORIES BEFORE USING. THEIR SPECIFIC INSTRUCTIONS ARE NOT INCLUDED IN THIS MANUAL.

USE THE AEM MONITOR ONLY IF THE SELF-TEST HAS BEEN PROPERLY COMPLETED. OTHERWISE, AEM FUNCTIONS MAY NOT BE OPERATIVE.

WHEN AN ALERT IS PRESENTED BY THE AEM MONITOR, DISCONTINUE USE OF THE ELECTROSURGICAL CURRENT IMMEDIATELY. FIND THE CAUSE OF THE ALERT AND CORRECT IT BEFORE CONTINUING USE.

AEM MONITORING WILL NOT FUNCTION WITHOUT THE USE OF DUAL PAD PATIENT RETURN ELECTRODES AND AN ELECTROSURGICAL UNIT EQUIPPED WITH CONTACT QUALITY MONITORING PATIENT SAFETY TECHNOLOGY.

DAMAGED INTERNAL INSULATION OF THE INSTRUMENT, OR LOSS OF SHIELD CONTINUITY, MAY CAUSE ESU RETURN PAD ALARMS TRIGGERED BY THE AEM MONITOR'S FAULT INDICATORS. FOR MAXIMUM PATIENT SAFETY, DISCONTINUE USE OF THE INSTRUMENT IF THIS OCCURS.

A SINGULAR AEM INSTRUMENT MUST BE THE SOLE CONDUCTOR OF ENERGY TO TISSUE. DO NOT CONDUCT ENERGY BY TOUCHING AN AEM INSTRUMENT TO A SECOND INSTRUMENT CONTACTING TISSUE. THE SECOND DEVICE WILL NOT BE PROTECTED FROM CAPACITIVE COUPLING AND INSULATION FAILURE.

LIMIT POWER SETTING TO 80 WATTS OR LOWER. OTHERWISE, SPURIOUS INSULATION FAILURE ALARMS MAY OCCUR.

GOOD OPERATING ROOM PRACTICE SUGGESTS THAT CONNECTIONS OF ACCESSORIES TO ELECTROSURGICAL GENERATORS BE MADE ONLY WHILE THE GENERATOR IS *OFF* OR ON *STANDBY*.

### Electromagnetic Compatibility Hazards

**Caution**

USE OF ACCESSORIES, TRANSDUCERS AND CABLES OTHER THAN THOSE SPECIFIED, WITH THE EXCEPTION OF TRANSDUCERS AND CABLES SOLD BY THE MANUFACTURER OF THE EQUIPMENT OR SYSTEM AS REPLACEMENT PARTS FOR INTERNAL COMPONENTS, MAY RESULT IN INCREASED EMISSIONS OR DECREASED IMMUNITY OF THE EQUIPMENT OR SYSTEM.

AEM MONITOR SHOULD NOT BE USED ADJACENT TO OR STACKED WITH OTHER EQUIPMENT EXCEPT AS SPECIFIED HEREIN. IF ADJACENT OR STACKED USE IS NECESSARY, THE EQUIPMENT SHOULD BE OBSERVED TO VERIFY NORMAL OPERATION IN THE CONFIGURATION IN WHICH IT WILL BE USED.

FOLLOW THE ELECTROSURGERY UNIT MANUFACTURERS INSTRUCTIONS AS FAR AS LOCATING EQUIPMENT WITHIN THE OPERATING ROOM TO DIMINISH OR ELIMINATE RADIO FREQUENCY ELECTRICAL INTERFERENCE WITH OTHER ELECTRONIC EQUIPMENT.

MEDICAL ELECTRICAL EQUIPMENT NEEDS SPECIAL PRECAUTIONS REGARDING EMC AND NEEDS TO BE INSTALLED AND PUT INTO SERVICE ACCORDING TO THE EMC INFORMATION PROVIDED IN THE ACCOMPANYING DOCUMENTS. PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT CAN AFFECT MEDICAL ELECTRICAL EQUIPMENT.

## Symbol Definitions

Attention: Consult accompanying documents

Ground

Type CF Equipment with defibrillator protection

Bipolar Jumper Cord

Bipolar Accessory

Remote Display Jack

REF Catalog Number

Date of Manufacture

Consult Instructions for Use

Power

AEM Cord Setup Fault

Return Electrode Setup Fault

Insulation Operative Fault

Ready

High

OFF Volume Control

Low

SN Serial Number

EC REP Authorised Representative in the European Community